

ORDER FOR SUPPLIES OR SERVICES						PAGE OF PAGES		
						1	17	
<b>IMPORTANT:</b> Mark all packages and papers with contract and/or order numbers.								
1. DATE OF ORDER 05/28/2019		2. CONTRACT NO. (If any) 68HERH19D0022		6. SHIP TO:				
3. ORDER NO. 68HERH19F0202		4. REQUISITION/REFERENCE NO. PR-OCSPP-19-00292		a. NAME OF CONSIGNEE  OCSPP DC				
5. ISSUING OFFICE (Address correspondence to) HQAD  US Environmental Protection Agency William Jefferson Clinton Building 1200 Pennsylvania Avenue, N. W. Mail Code: 3803R Washington DC 20460				b. STREET ADDRESS USEPA OCSPP (Division), MC: RM: WJC East Building 1201 Constitution Ave, NW		c. CITY Washington		
				d. STATE DC		e. ZIP CODE 20004		
7. TO: David Sprague				f. SHIP VIA				
a. NAME OF CONTRACTOR SRC, Inc.				8. TYPE OF ORDER				
b. COMPANY NAME				<input type="checkbox"/> a. PURCHASE REFERENCE YOUR:  Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.		<input checked="" type="checkbox"/> b. DELIVERY  Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.		
c. STREET ADDRESS 7502 ROUND POND ROAD								
d. CITY NORTH SYRACUSE		e. STATE NY		f. ZIP CODE 132122558				
9. ACCOUNTING AND APPROPRIATION DATA See Schedule				10. REQUISITIONING OFFICE				
11. BUSINESS CLASSIFICATION (Check appropriate box(es))						12. F.O.B. POINT		
<input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone  <input type="checkbox"/> f. SERVICE-DISABLED VETERAN-OWNED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM <input type="checkbox"/> h. EDWOSB								
13. PLACE OF		14. GOVERNMENT B/L NO.		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)		16. DISCOUNT TERMS		
a. INSPECTION Destination		b. ACCEPTANCE Destination						
17. SCHEDULE (See reverse for Rejections)								
ITEM NO. (a)	SUPPLIES OR SERVICES (b)			QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: 063053771 Environmental Hazard and Risk Assessment Support for New Chemicals under TSCA 68HERH19D0022/68HERH19F0202 (formerly RFTOP Task Order 14)  Continued ...							
SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		\$225,000.00	17(h) TOTAL (Cont. pages) ◀
	21. MAIL INVOICE TO:							
	a. NAME		RTP Finance Center					
	b. STREET ADDRESS (or P.O. Box)		US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts				\$3,403,922.18	17(i) GRAND TOTAL ◀
c. CITY Durham		d. STATE NC		e. ZIP CODE 27711				
22. UNITED STATES OF AMERICA BY (Signature)				05/28/2019		23. NAME (Typed) Derek Davis TITLE: CONTRACTING/ORDERING OFFICER		

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

PAGE NO  
2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 05/28/2019	CONTRACT NO. 68HERH19D0022	ORDER NO. 68HERH19F0202
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0001	<p>TO COR : Kara Koehn 202-566-0310 koehn.kara@epa.gov</p> <p>Alt. TO COR: Clifton Townsend 202-564-1576 townsend.clifton@epa.gov</p> <p>TOCOR: Kara Koehn Max Expire Date: 05/27/2024</p> <p>Admin Office: HQAD US Environmental Protection Agency William Jefferson Clinton Building 1200 Pennsylvania Avenue, N. W. Mail Code: 3803R Washington DC 20460</p> <p>Period of Performance: 05/28/2019 to 05/27/2020</p> <p>Base Year: Task Order Type: T&amp;M Hours 6856.00 NTE: \$655,208.18 Period of Performance: 05/28/2019 - 05/27/2020</p> <p>Accounting Info: 18-19-B-69A-000CD6-2505-QT5PSMZ-TC5PQ QH-1969AC9021-001 BFY: 18 EFY: 19 Fund: B Budget Org: 69A Program (PRC): 000CD6 Budget (BOC): 2505 Job #: QT5PSMZ Cost: TC5PQQH DCN - Line ID: 1969AC9021-001 Funding Flag: Partial Funded: \$150,000.00</p> <p>Accounting Info: 19-20-B-69A-000CD6-2505-TC5PQQH-1969AC 9021-002 BFY: 19 EFY: 20 Fund: B Budget Org: 69A Program (PRC): 000CD6 Budget (BOC): 2505 Job #: QT5PSMZ Cost: TC5PQQH DCN - Line ID: 1969AC9021-002 Funding Flag: Partial Funded: \$75,000.00</p>				225,000.00	
0002	<p>Option 1 Task Order Type: T&amp;M Hours 6856.00 Continued ...</p>				Option	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$225,000.00

# ORDER FOR SUPPLIES OR SERVICES

## SCHEDULE - CONTINUATION

PAGE NO  
3

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 05/28/2019	CONTRACT NO. 68HERH19D0022	ORDER NO. 68HERH19F0202
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	NTE: \$668,315.01 Period of Performance: 05/28/2020 - 05/27/2021 (Option Line Item)					
0003	Option 2 Task Order Type: T&M Hours 6856.00 NTE: \$681,694.01 Period of Performance: 05/28/2021 - 05/27/2022 (Option Line Item)				Option	
0004	Option 3 Task Order Type: T&M Hours 6856.00 NTE: \$695,331.01 Period of Performance: 05/28/2022 - 05/27/2023 (Option Line Item)				Option	
0005	Option 4 Task Order Type: T&M Hours 6856.00 NTE: \$703,373.97 Period of Performance: 05/28/2023 - 05/27/2024 (Option Line Item)				Option	
	The obligated amount of award: \$225,000.00. The total for this award is shown in box 17(i).					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00



## **ENVIRONMENTAL PROTECTION AGENCY**

### **Environmental Hazard and Risk Assessment Support for New Chemicals**



**CONTRACTOR:** 68HERH19D0022

**TASK ORDER NUMBER:** 14

**PROJECT TITLE:** Environmental Hazard and Risk Assessment Support for New Chemicals

<u><b>Task Order Contracting Officer's Representative</b></u>	<u><b>Alternate Task Order Contracting Officer's Representative</b></u>
Kara Koehn USEPA/OCSP/OPPT/RAD 1200 Pennsylvania Avenue, NW Mail Code 7410M Washington, DC 20460 Phone: (202) 566-0310 <a href="mailto:Koehn.Kara@epa.gov">Koehn.Kara@epa.gov</a>	Clifton Townsend USEPA/OCSP/OPPT/RAD 1200 Pennsylvania Avenue, NW Mail Code 4607M Washington, DC 20460 Phone: (202) 564-1576 <a href="mailto:Townsend.Clifton@epa.gov">Townsend.Clifton@epa.gov</a>

## **A. Performance Work Statement (PWS)**

### **A1. Background and Purpose**

#### Background

The Risk Assessment Division (RAD) of the USEPA Office of Pollution Prevention and Toxics (OPPT) is responsible for health and environmental hazard/risk assessment of chemicals regulated under The Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends the Toxic Substance Control Act (TSCA) <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.

This task order is supporting the implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Since the inception of the New Chemicals Review Program under the Toxic Substances Control Act (TSCA) in 1979, OPPT has received over 42,000 premanufacture notices (PMN). PMNs must include data specified in 40 CFR Part 720 and on the PMN form regarding chemical identity, impurities, synonyms/trade names, byproducts, production volume ("PV"), uses, and site information including identity, process descriptions, worker exposure information, information on release to the environment, including the quantity and media of release and control technology used. 40 CFR § 720.50 requires submission of test data in the possession or control of the submitter, parent company, or affiliates, which are related to the effects on human health or the environment. Other data concerning the human health and environmental effects of the new chemical substance that are known to, or reasonably ascertainable by, the submitter must also be described by the submitter as part of the PMN.

The data and information submitted with the PMN submissions undergo a review process. RAD is responsible for conducting a risk assessment to determine whether the new chemical substance presents an unreasonable risk of injury to human health or the environment. As part of developing the risk assessment, RAD evaluates the data and information submitted with the PMN submission (e.g., test data) as well as uses predictive methods (e.g., expert systems, in silico methods, analog analysis, read across, quantitative structure activity relationships (QSARs)) to estimate the risks of the new chemical substance. The latter is conducted in response to the data-poor situation encountered with many PMNs submitted to the agency. Each PMN has a 90-day regulatory review period, including the risk determination. Technical review must occur in a timely fashion for EPA to complete the regulatory process.

#### Purpose

The primary purpose of this task order is to assist with the technical review, including but not limited to, the extraction, summary, and use of environmental hazard data to support the risk determination for new chemicals.

RAD also regularly develops and updates the predictive methods and pertinent databases to support decision making under TSCA. This task also supports the development and update of predictive methods that support the estimation of environmental hazard and/or risks of new chemicals. Specifically, contractor will support the following activities:

- 1) Extract all environmental hazard information submitted with new chemical notices and input the information into appropriate databases;
- 2) Extract all environmental hazard information submitted after the initial review process as directed and input the information into the appropriate databases;
- 3) Conduct a scientific review of the environmental hazard information to determine the quality, completeness and suitability of the data/information, as directed;
- 4) Provide a written review of the toxicological information as directed;
- 5) Maintain and resolve any technical problems with the health databases as they arise; and
- 6) Use of the captured information for tool update and development when directed.

The Contractor will also develop other technical products from the submitted data/information or those already in EPA's internal database. Examples of these other activities include, but are not limited to, hazard assessments, generation of model inputs and outputs (where appropriate), model maintenance, Quality Assurance and/or Quality Control project plans and/or of other technical work products within the scope of Task Order 8. The details will be explained in Task order 14.

## **A2. Scope of Work**

The purpose of this procurement is to provide support for environmental hazard assessment of new chemicals for OPPT.

The contractor will be required to have the ability to work on-site in the CBIC or other CBI secured spaces in an EPA building. The contractor may also be given tasks that can be performed remotely and would need to have CBI secured space for those activities. The contractor will have access to CBI machines for the performance of new chemical reviews. The contractor shall supply the necessary resources required for the performance of non-CBI tasks (database searching). The scientific quality of assessments, reports, model tools, statistical programs and software, and their timely preparation in accordance with new chemical program schedules, are of paramount importance in the performance of this contract.

The contractor shall have the necessary technical and scientific expertise, knowledge and experience to successfully perform all of the tasks identified below. In addition, the contractor shall have a quality assurance/quality control program that maintains the quality of products, as well as an ongoing training program. This is intended to ensure that the contract staff produces quality products, and feedback from OPPT on needed improvements is communicated to the contractor's staff. The contractor shall maintain and make available upon request complete documentation of QA/QC practices and procedures.

Performance of work under this contract shall be initiated by competitive task orders issued by the Contracting Officer, and will encompass tasks in following areas discussed below in Section C.3 (TASKS).

The contractor may receive EPA laptops to facilitate completion of tasks in this task order at the discretion of the CO and TOCORs.

## **B. TASKS**

### **TASK 1: Project Management and QAPP requirements**

#### **Project Management**

The contractor shall provide a Project Manager. The Contractor Project Manager shall report on all aspects of the objectives and progress of this contract to the designated EPA Contracting Officer (CO) and Task Order Contracting Officer Representative (TOCOR) via email, through monthly reports. The Contractor Project Manager also plans, conducts and supervises Task Order (TO) projects, necessitating advanced knowledge and the ability to originate and apply new and unique methods and procedures. The Contractor Project Manager provides advice and counsel to other professionals. The Contractor Project Manager shall notify via email the relevant EPA TOCOR/Alternate TOCOR of any significant difficulties in accomplishing the task listed in the

TOs.

In cases where performance objectives and minimum Acceptable Quality Levels (AQLs) are not being met, the Contractor Project Manager will make every effort to immediately correct the problems to ensure customer satisfaction. If the problem persists, the Project Manager will submit a plan of corrective action to the TOCOR and the Contract Level COR. The Contractor Project Manager shall ensure that the approved Quality Assurance (QA)/Quality Control (QC) process is followed to ensure the quality of its products.

### **QAPP Requirements**

Quality Assurance: The Quality Management Plan, the QAPP for Tasks 2 through 5. The contractor shall adhere to its Quality Management Plan that is tailored for this contract.

This Task Order involves the use of existing data. Accordingly, EPA policy requires that an approved Quality Assurance Project Plan (QAPP) be in place before any work begins that involves the collection, generation, evaluation, analysis or use of environmental data. The QAPP must be consistent with EPA Requirements for Quality Assurance Project Plans: EPA QA/R-5 (<https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf>).

- The contractor shall prepare and submit for EPA review a draft Quality Assurance Project Plan (QAPP) for Tasks 2 through 5 within 10 days of selection and before **the initiation of the rest of the task order**. Updates to QAPP based on comments from the EPA to the QAPP must be received within 3 working days.
- EPA will review the contractor's draft QAPP and provide the Contractor with written approval or written comments.
- If needed, the Contractor shall submit a revised QAPP within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TOCOR. An acceptable QAPP must be received before the rest of the task order is initiated (tasks 2-5, no funds may be received for the following tasks until the contractor's QAPP has been approved).
- Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed by the contractor until the contractor receives written notification from the EPA TOCOR that EPA has approved the contractor's QAPP.

All QA documentation, including the QAPP, prepared under this TO, shall be considered non-proprietary, and shall be made available to the public upon request.

### **Additional QA Documentation Required**

In addition to the requirements described above, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) produced by the Contractor under this Task Order must include a discussion of the QA/QC activities that were or will be performed to support the deliverable. The contractor shall immediately notify the EPA TOCOR of any QA problems encountered that may impact the performance of this Task Order, with recommendations for corrective action.

The contractor also shall provide EPA with monthly reports of QA-related activities performed during implementation of this Task Order. These monthly QA reports shall identify QA activities performed to support implementation of this task order, problems encountered, deviations from the QAPP, and corrective actions taken. The contractor may include this as a part of the contract-required monthly financial/technical progress report. The contractor shall notify the EPA TOCOR at any time during the task order if changes to the QAPP are warranted (e.g., due to organizational changes, revised technical approaches).

If, during the Period of Performance of this Task Order, the EPA TOCOR determines revisions to the QAPP are necessary, the contractor shall submit a revised QAPP, including the revision summary, within 5 business days after receiving written technical direction to do so. EPA will review the draft revised QAPP and provide the

contractor with written approval or comments. The contractor shall provide a revised QAPP, then a final QAPP that responds to EPA's written comments within 5 business days of receipt of EPA's comments on the draft QAPP.

- Under no circumstances shall work involving environmental data be performed by the contractor until the contractor receives written notification from the EPA TOCOR that EPA has approved the contractor's QAPP.

Since this task order involves the collection, evaluation, and use of environmental data by and for the Agency, the contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following EPA guidelines. QAPP is due within 10 days of task order award.

## **TASK 2. Reporting Requirements**

The contractor shall write and submit monthly progress reports to the EPA Task Order Contracting Officer Representative (TOCOR). Progress reports shall describe completed work during the invoice period and should link to charges described in invoice documentation.

Routine progress reports shall include a written monthly technical progress report that includes the following in the case of each project that the contractor is involved in during the month: (a) an overview of work accomplished since project inception to to-date (b) a description of work accomplished during the month, (c) a summary of QA/QC activities since project inception including a summary of corrective action taken (d) a brief summary of anticipated work during the following month, (e) a summary and details of the costs incurred for each task during the month and cumulatively, and (f) total remaining budget. This report shall also be issued to the Contract Level COR. Routine progress reports shall be delivered electronically; paper copies are not needed. The Contractor shall notify the TOCOR and CO when 75, 90, and 100% of approved budget has been expended. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained. Work not related to environmental data operations such as scoping how environmental data may be searched for or summarized once available including refinement of keywords, criteria, or report templates may begin prior to QAPP approval.

Failure to submit monthly progress reports with the information required will result in the suspension of the invoice until such supporting documentation is provided. Any deviations from the project such as work schedules, impediments encountered, and budget require approval from the EPA CO. The EPA CO may also initiate verbal communications with the contractor on an as needed basis to determine project status.

**Deliverable:** Monthly Progress Reports shall be submitted to the EPA TOCOR within three (3) calendar days of invoice submission to EPA. Minimal level of effort required for this deliverable.

## **TASK 3: Developing Ecotoxicity Hazard Assessments for the New Chemicals Program**

The contractor shall support eco assessors in meeting the objectives of this task order and its responsibilities under TSCA Section 5 by performing the following:

### **3.1 Ecotox CRSS list**

Once the CRSS list is released, contractors shall populate the ecotox list of cases and the corresponding information as shown below and outlined in the QAPP. Open the new chemical submission in OPPT's CIS system to look for data, Sustainable Future submissions (may include data), and any other relevant information provided in the initial submission. Make sure to review Part III of the new chemical submission form (attachments) to see if submitters indicate data was submitted. If there is a mention of data in the new chemical submission but it is not attached in CIS, contact the Chemical Control Division (CCD) so they can follow-up with the company.

The CRSS list should then be saved by CRSS data and uploaded to the following folder:

J:\ECO New Chemical/2019/CRSS list/

Note: The folder year will change depending on fiscal year.

Important Note for Case Prep: Have Industrial Chemistry Branch (ICB) support chemists report out on any changes/notes discussed in the CRSS meetings to the RAD ecotox support contract team. This information will help the ecotox contractors determine cases to address for the subsequent Pre-SAT and SAT meeting.

- Note any new additions to the agenda (referred to as ‘bring-backs’ on the CRSS schedule which become part of the subsequent SAT meeting).
- Note any delays, or incompletes; these will NOT go forward to SAT (meaning it is no longer part of the required reports for the subsequent SAT meeting but may reappear in future CRSS lists).
- Note any same-as cases or structural analogues identified during the CRSS meeting.

Update the CRSS list with any changes (i.e. bring-backs, incompletes or delays). If present, make sure experimental data is noted for the bring-back cases.

Once the CRSS list is prepped, the contractor will begin developing the ecotox hazard profiles for each new chemical listed using a combination of approaches including measured experimental data on the PMN, identification of analogues and read-across approaches and application of in silico estimation approaches as described below.

### **3.2 Extracting and presenting available measured data provided by the submitter or identified in archived data through “same-as” cases**

As described in the QAPP, once experimental data has been identified by SRC for the submission of “same-as” case, preliminary endpoints should be extracted into the PMN Ecotoxicity database and presented in tables at the Pre-SAT Ecotox Meeting (see calendar for appropriate days).

After the data extraction for pre-SAT and to the DB, the contractor shall draft individual study summaries in a single WORD document which follows the general outline below. The summaries ARE NOT required to be completed by the Pre-SAT Meeting, but they will be due a day or two after SAT. Following QC, SRC will place the studies and summaries in corresponding folder on the J: drive of EPA’s CBI LAN. A non-CBI email will be sent to the TOCOR, Alternate TOCOR, and EPA assessor notifying her/him of the delivery of the document, and a CBI email will be sent to the TOCOR, Alternate TOCOR, and EPA assessor with the location of the documents.

For “same-as” cases, measured data, study summaries, and the SAT report should be included in the J: drive folder of the new case, and be labeled as such to avoid confusion.

The calendar found in Appendix 1 provides specific due dates. The EPA eco assessors will then validate the studies provided and finalize the summaries and update the eco profile and final report as needed between SAT and FOCUS.

The contractor shall extract and summarize all toxicological data received after initial review as directed by the TOCOR. The data shall be entered into the PMN Ecotox DB as required. All toxicological data should be calculated for 100% active ingredient (100% AI) if possible, or state that % AI cannot be determined. The contractor shall also summarize the toxicological data in formats outlined by the TOCOR to evaluate whether the study meets the relevant criteria for rigor and adequacy, as described in the OPPT Harmonized Test Guidelines, found at: <https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-850-ecological-effects-test-guidelines>.

### **Example Template for Study Summaries**

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Case Number  
 Chemical Name  
 Trade Name (if available)  
 CAS Registry Number (if available)  
 Initial Submission/Post Focus Review

#### **Study 1: (Repeat for each Study Submitted)**

- Summary Sentence of Study Details
  - Duration, Species, Laboratory, Case number, Purity of Test Substance, Nominal/Measured
- Guideline Reference
- Number of Replicates
- How was the Test Solution Prepared?



- Sonication, shake flask, filtration, centrifuge, etc.
- See OPPTS Guidelines for testing difficult substances for more examples
- Nominal/Mean Measured Test Concentration Values
  - Measured values and subsequent results are preferred over nominal – if both are provided summarize only measured details
- Analytical Monitoring Methods
  - What method was used to quantify substance concentration in solution, if measured concentrations were done (HPLC/UV, etc.)
- Nominal versus Mean Measured Concentrations (MM = %N)
- Study Observations on Mortality and Sub-Lethal Effects
- Temp Range/pH range/DOC/TOC or Water Hardness
- Study Results (LC50/EC50/NOEC/LOEC/ChV) – see chart below for preferred endpoints per organism/study to be highlighted in eco summary.

REPEAT AS NEEDED FOR OTHER STUDIES

**Ecotox Summary provided by SRC:**

Contractor Name

Date

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### 3.3 Applying in silico Predictive Approaches

The contractors shall develop a preliminary predicted aquatic toxicity profile for each new chemical submission based on the approaches outlined in the QAPP with the exception that all new ECOSAR predictions should be carried out on the updated and recently released Version 2.0 of ECOSAR. The QAPP workflow describes the process for deriving predictions that incorporates how a predictive approach is selected and aquatic hazard is determined according to the predictive methodology employed (i.e., polymer, discrete organic, inorganic) to establish an aquatic hazard profile.

For polymers with Low Molecular Weight (LMW) oligomers (<1,000); when multiple oligomers are run, use the most conservative predictive values available across all run (not only the values for the smallest oligomer).

### 3.4 Identifying Analogues to Fill Data Gaps

The contractor shall conduct analogue searches based on the structure of the submitted chemical and any “structurally related” substances identified by contractor chemists. Good analogues will have shared functionalities, and structural commonality should focus on the most reactive sites of the molecule, which often drive hazards. For example, alkyl chains are non-reactive functionalities that simply change the p-chem properties. However, electrophilic or nucleophilic groups will often lead to reactions in the body resulting in subsequent damage to a system. The sources used to search for analogues should include the following resources only, in the order listed, unless instructed otherwise by the EPA TOCOR. Not all cases will require searching in all these sources and should be followed when predictions are incomplete or uncertainty is high, so the overall search strategy will be left up to the contractors preparing the cases.

1. Analog Identification Methodology (AIM) – CBI version
2. ECHA Database/REACH information<sup>1</sup>

FOR ALL ANALOGUE DATA SURVEYED DURING PROCESS – If the contractor finds any discrepancies/inconsistencies in the way a certain chemical class/type of analogues have been previously evaluated (e.g. difference in acute/chronic values employed and COCs used), please report those findings back to the TOCOR and the eco assessor, so they can be resolved by the ecotox risk assessment team as soon as possible.

An analogue search IS NOT necessary if there is:

- Measured acute and/or chronic base set

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<sup>1</sup> If the test data is unclear, and the contractor can't tell whether the actual discreet substance was tested or if an analogue approach of hydrolysis products were used instead, ECHA data should be used with caution and uncertainty be communicated to eco assessor before entering it into the report.

- Same-as case with adequate data

An Analogue search IS necessary if there is:

- No experimental data
- ECOSAR predictions are contra-indicated

The contractor shall not spend more than 30 minutes identifying analogues, to make the best use of time. If no analogues data, predictions, or measured data are available, it is acceptable to indicate the chemicals has a “data gap” which may support an “insufficient information” finding for the EPA

The mol file can be used to search for analogues or which was used in ECOSAR. SMILES notation can be used to acquire the structure before the mol file is available.

### **3.5 Creating an Ecotox Report in NCR**

The contractor shall assemble all the information from the above subtasks and create an Ecotox Report in NCR. An example of the report and instructions for entry of the data and information are included in Appendix 2.

Note that if multiple acute and/or chronic values are available (e.g. ECOSAR, same-as data and/or data from another source), the contractor should only enter the most conservative value and add comment as to its source in the comment section. At the pre-SAT meeting the contractor will let the eco assessor know the rationale for its use. IF, however, a question exists about which value to use (e.g. when multiple hydrolysis product exists), no value should be entered into the table and questions should be brought to the assessor during the pre-SAT meeting.

### **3.6 Creating a “Case Folder” on the CBI LAN and saving all subsequent work products and supporting information for each case**

Within the folder J:\ ECO New Chemical/2019/PMN Number/

Under the PMN Number, a case could potentially have 2 subfolders titled “CRSS/SAT” and “DATA Summary”:

- CRSS/SAT Folder
  - Included will be all relevant supporting documents generated from the NCR profile by the chemist and biologists. Information contained in this folder will include items such as:
    - PDF copy of the ecotox report
    - PDF ECOSAR predictions with structure
    - Data sheet extractions (if experimental data was provided for a case)
    - Same-as data if available
    - Analogue(s) table with known data and 1-2 line description on what makes this a good analogue
    - Hydrolysis and other degradation products information
    - Reports from online public sources
    - Other

These documents to be discussed further as the work progresses.

- DATA Summary Folder
  - Included will be the summary write-up of the experimental data and corresponding original studies. Contractors should maintain separate folders for “Initial Submission” data (provided with initial PMN) and “Post-Focus” data reviews (data submissions after initial PMN Review)
  - These data summary folders already exist on the J:drive for older cases and they will be moved over to this file structure for archiving.

The contractor shall provide EPA these files electronically to the share folders above, and all files will be saved as read only. If EPA staff choose to print hard copies of the documents they must do so themselves.

For “same-as” cases, the contractor shall include copies of the SAT report for those “same-as” cases.

### **3.7 Attending Ecotox Pre-SAT Meetings to present all cases and discuss with assigned EPA Ecotox Assessor and/or EHAT team**

The contractor shall prepare and present ecotoxicity hazard calls along with any relevant supporting information (e.g., submitted data, analogues, mitigation factors, and/or information available on same-as or analogues) at the

Pre-SAT Ecotox meetings occurring at 11:00 AM ET on Mondays and at 10:30 AM ET on Thursdays in Room 6353. The contractor staff are responsible for understanding and communicating to EPA's assigned eco assessor how the hazard profile values were selected or derived for each case going to SAT the next day. The contractor will discuss the profiles and any outstanding questions with the EPA eco assessor, help address any questions that arise from the ecotox group members in attendance and will be recording/making any required changes to the NCR ecotox profile. The contractor will present all hazard value sources that were evaluated, and explain how the hazard profile values were selected or derived for each case going to SAT the next day, when applicable.

The calendar provided in Appendix 1 provides a 4-week example of the meetings and deliverables.

#### **TASK 4: Support of Predictive model and/or tool development**

The contractor shall also support predictive model and/or tool development through collection, evaluation, and validation of the toxicological data described above to support enhancements to OPPTs predictive models as directed by the TOCOR. This may include: Investigating new QSARs to add to ECOSAR which may include QSARs for new organics classes, polymers, surfactants, dyes, inorganic chemicals, organometallics, perfluorinated elements, and metals; and drafting or revising documentation such as the new QSAR manual sheets to support the new algorithms or approaches.

#### **TASK 5: Supplemental Support on PMN Environmental Hazard Assessment Under TSCA Section 5**

The contractor may be directed to provide support in the development of documents and other activities to support management decision making, implementing LEAN process, developing/updating manuals for Ecotoxicity Team internal use in RAD, and developing interim documents, study/protocol review guidance, and other documents.

#### **C. REPORTING REQUIREMENTS AND SCHEDULE OF BENCHMARKS & DELIVERABLES:**

As described in Task 2 and in the invoice instructions, the Contractor shall provide a monthly report CO, COR and TOCOR which identifies project staff and all activities and milestones associated with the Task Order assignments planned and in progress. The monthly report in progress tasks shall be included in the monthly reports which will be referenced when the Voucher Validation review is performed monthly at the end of each billing cycle.

As per the Task Order or request for a proposal, the Contractor shall provide the Agency with a proposal within the timeframe specified for this Task Order. The EPA CO, TOCORs, or panel members will review the proposal and provide the Contractor with an approval or disapproval, and revision (if necessary) in writing. The timelines involved, will proceed as stipulated in the request for a proposal or Contract

The Contractor shall prepare a Quality Assurance Project Plan for this Task Order. EPA Requirements for Quality Assurance Project Plans (QA/R-5).

For most deliverables, the EPA TOCOR will assign a tentative due dates and instructions when work is routed to the Contractor. If within three business days, the Contractor expresses no concern regarding the due date; the date shall be deemed settled by tacit agreement.

#### **SPECIFIC SCHEDULE OF DELIVERABLES:**

<b>Tasks</b>	<b>Deliverables</b>	<b>Schedule</b>
Task 1:	Project Management and QAPP	QAPP within ten days of task order award
Task 2:	Monthly progress reports	Monthly reports



Tasks	Deliverables	Schedule
Task 3:	Developing Ecotoxicity Hazard Assessments for the New Chemicals Program	Products shall be submitted within the same day as the contractor is tasked with the work.
Task 4:	Model Maintenance	Products shall be submitted based on technical direction issued by the TOCOR.
Task 5:	Supplemental Support on Ecological Assessment	Products shall be submitted based on technical direction issued by the TOCOR.

#### D. DELIVERABLES

For each deliverable submitted electronically, the contractor shall submit electronic copies to EPA in a format that EPA can support. Deliverables shall be submitted through electronic mail, or through another method determined mutually acceptable by the contractor and EPA.

#### E. ACCEPTABLE QUALITY LEVEL FOR TASKS

See Attachment: Quality Assurance Surveillance Plan

Performance Criteria Analysis – TASKS		
Performance Indicator	Standard	Acceptable Quality Level (AQL)
Timely submission of report	Reports submitted within time frame pre-negotiated with Task Order COR	95%
Free of substantive technical, guideline, or format errors	Reports submitted with zero substantive errors including but not limited to discrepancies, omissions, inaccuracies, and/or inappropriate data evaluation	95%

##### E.1 Method of surveillance

Final deliverables prepared by the contractor undergo a secondary review process in OPPT. Each report has a designated EPA reviewer. The EPA reviewer conducts a review of the contractor's deliverable. The EPA reviewer will provide feedback to the TOCOR to send back to the contractor should revisions be needed. The TOCORs will compare agency due dates or approved revised due dates to completed date of reports, quarterly and calculate the percentage of late reports. See attachment J.5 of this RFTOP.

##### E.2 Period of Performance

The period of performance of this task order is:

- Base: 12 months from award date
- Option 1: 12 months from option exercise
- Option 2: 12 months from option exercise
- Option 3: 12 months from option exercise
- Option 4: 12 months from option exercise

## **F. TASK ORDER TYPE**

Time and materials

## **G. INSPECTION AND ACCEPTANCE**

### **G.1 Quality Assurance Project Plan**

The contractor shall submit the following quality system documentation to the CO at the time frames identified below:

	<b>Documentation</b>	<b>Specifications</b>	<b>Due</b>
X	Quality Assurance Project Plan for the Task Order	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/11]	Task Order proposal due date

This documentation can be found on the following EPA website – <https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans>

This documentation will be prepared in accordance with the specifications identified above or equivalent specifications defined by EPA.

The Government will review and return the quality documentation, with comments, and indicating approval or disapproval. If necessary, the contractor shall revise the documentation to address all comments and shall submit the revised documentation to the government for approval.

The contractor shall not commence work involving environmental data generation or use until the Government has approved the quality documentation.

## **H. TASK ORDER ADMINISTRATION DATA**

### **H.1 Contract Administration Representatives**

Contracting Officer: Genine McElroy, [McElroy.Genine@epa.gov](mailto:McElroy.Genine@epa.gov)

Contract Level Contracting Officer's Representative: Bryan Lobar, [lobar.bryan@epa.gov](mailto:lobar.bryan@epa.gov)

Task Order Contracting Officer's Representative (TOCOR): Kara Koehn, [Koehn.kara@epa.gov](mailto:Koehn.kara@epa.gov)

Alternate TOCOR: Clifton Townsend, [Townsend.Clifton@epa.gov](mailto:Townsend.Clifton@epa.gov)

## **I. INVOICING**

Invoices shall be submitted in accordance with contract clause G.3 EPAAR 1552.232-70 SUBMISSION OF INVOICES. (JUN 1996) - ALTERNATE I (JUN 1996).

(End of Clause)

## **J. TASK ORDER CLAUSES**

### **J.1 FAR 52.217-9 Option to Extend the Term of the Contract (Mar 2000)**

(a) The Government may extend the term of this contract by written notice to the contractor within 5 calendar days before the expiration of this contract; provided that the Government gives the contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 Months. (End of clause)

**J.2 LOCAL CLAUSE EPA-B-32-103A LIMITATION OF GOVERNMENT'S OBLIGATION**

- (a) Severable services may be incrementally funded. Non-severable services shall not be incrementally funded. Contract line items 0001 through 0005 are severable and may be incrementally funded. For these items, the sum of \$225,000.00 of the total price is presently available for payment and allotted to this contract.
- (b) For items identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including reimbursement in the event of termination of those items for the Government's convenience, approximates the total amount currently allotted for those items to the contract. The Contractor shall not continue work on those items beyond that point. Subject to the clause entitled, "Termination for Convenience of the Government," the Government will not be obligated, under any circumstances, to reimburse the Contractor in excess of the amount payable by the Government in the event of the termination of applicable contract line items for convenience including costs, profit, and estimated termination costs for those line items.
- (c) Notwithstanding the dates specified in the allotment schedule in paragraph (h) of this clause, the Contractor will notify the Contracting Officer, in writing, at least 5 days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85% of the total amount currently allotted to the contract for performance of the applicable items. The notification will state (1) the estimated date when that point will be reached and (2) an estimate of additional funding, if any, needed to continue performance of the applicable line items up to the next scheduled date for the allotment of funds identified in paragraph (a) of this clause, or to a substitute date as determined by the Government pursuant to paragraph (d) of this clause. If, after such notification, additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the clause entitled "Termination for Convenience of the Government."
- (d) The parties contemplate that, subject to the availability of appropriations, the Government may allot additional funds for continued performance of the contract line items identified in paragraph (a) of this clause and will determine the estimated period of contract performance which will be covered by the funds. If additional funds are allotted, the Contracting Officer will notify the Contractor in writing. The Contractor shall not resume performance of the contract line items identified in paragraph (a) until the written notice is received. The provisions of paragraphs (b) through (d) of this clause will apply in like manner to the additional allotted funds and to the new estimated period of contract performance. The contract will be modified accordingly.
- (e) The Government may, at any time prior to termination, allot additional funds for the performance of the contract line items identified in paragraph (a) of this clause.
- (f) The termination provisions of this clause do not limit the rights of the Government under the clause entitled "Default". The provisions of this clause are limited to the work and allotment of funds for the contract line items set forth in paragraph (a) of this clause. This clause no longer applies once the contract is fully funded.
- (g) Nothing in this clause affects the right of the Government to otherwise terminate this contract pursuant to the contract clause entitled "Termination for Convenience of the Government".
- (h) The parties contemplate that the Government may obligate funds to this contract in accordance with the following schedule:

RECAPITULATION:

	PRIOR AMOUNT	THIS MOD.	NEW AMOUNT
BASE PERIOD			
Total Maximum Amount:	\$0	\$0	<b><u>\$655,208.18</u></b>
Funded Amount:	\$0	\$0	<b><u>\$225,000.00</u></b>

**L-1 EPA-J-52-101 LIST OF ATTACHMENTS**

ATTACHMENT 1: QUALITY ASSURANCE SURVEILLANCE PLAN

## QUALITY ASSURANCE SURVEILLANCE PLAN

PERFORMANCE REQUIREMENT	PERFORMANCE MEASURE (PM)	PERFORMANCE STANDARD	SURVEILLANCE METHOD	INCENTIVES & DISINCENTIVES
<u>MANAGEMENT AND COMMUNICATION:</u> The contractor shall maintain contact with the EPA CO, COR, and TOCOR throughout the performance of the contract.	Contractor shall immediately bring potential problems to the appropriate EPA personnel and shall recommend actions that would mitigate or resolve the problem.	Issues that impact project schedules and costs shall be brought to the attention of the EPA within 3-days of occurrence.	All active task orders will be reviewed by the EPA to identify unreported issues.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Business Relations in the Contractor Performance Assessment Reporting System (CPARS).
<u>TIMELINESS:</u> For every Task Order awarded establishing a firm, specific delivery date for the generation of a report, the contractor shall deliver such report to the COR, TOCOR and CO no later than the time specified in the order's PWS.	Deliverables and related work must comply with contractual timeliness requirements. The contractor will be evaluated on its responsiveness to all task orders.	95% of all deliverables and related work shall be completed on time within task schedule and/or tech. direction requirements.	100% inspection of all deliverables and related work by the TOCOR; TOCOR will document the timeliness of all work requirements.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Timeliness in the Contractor Performance Assessment Reporting System (CPARS).
<u>TECHNICAL QUALITY:</u> For every task order awarded, the analyses conducted by the contractor shall be factual, defensible, credible, and based on sound scientific methods. All data shall be collected from reputable sources and quality assurance measures shall be conducted in accordance with the agency requirements outlined in the task orders.	All deliverables and related work must be complete, accurate, thorough, and professionally credible.	Data are 100% accurate; review demonstrates a high level of expertise and credibility with regard to personnel and use of scientific methodology. Task Orders shall be conducted in strict conformance with approved QA plans. Outputs shall withstand internal review by the US EPA and outside scientific reviewers.	EPA Staff will conduct secondary reviews of work completed by the contractor. Feedback will be provided.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation in the category of Quality of Product or Service in the Contractor Performance Assessment Reporting System (CPARS).